



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 16 2008

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs
Bayer HealthCare LLC,
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

RE: Notification for Label Revisions
EPA Reg. No.: 11556-131
Date of Submission: June 02, 2008

Dear Dr. Spilker:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated June 2, 2008, for the product CyLence Ultra Insecticide Cattle Ear Tag. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

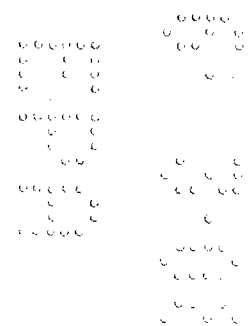
Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

Via Federal Express 06/02/2008

**Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501**

Enclosure:

- Application for Pesticide Notification for CyLence Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)
- Five copies draft labeling
- One highlighted copy draft labeling



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-131	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer Healthcare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. NOTIFICATION Product Name JUL 16 2008	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Enclosed with this Application for Pesticide Notification is a draft label for CyLence Ultra Insecticide Cattle Ear Tag, dated May 28, 2008, which has been modified only to change those items that fall under the scope of Pesticide Registration Notice (PRN) 98-10, PRN 97-5 or may be accomplished as Non-notifications. See attachment for further detail.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Douglas A. Spilker, Ph.D	Title Manager, EPA Reg Affairs	Telephone No. (Include Area Code) (913) 268-2751
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, EPA Regulatory Affairs	
4. Typed Name Douglas A. Spilker, Ph. D.	5. Date 2 June 2008	

ATTACHMENT FOR
APPLICATION FOR PESTICIDE REGISTRATION

June 2, 2008

CyLence® Ultra Insecticide Cattle Ear Tag (EPA Reg. No. 11556-131)

Enclosed with this Application for Pesticide Notification is a draft label for CyLence Ultra Insecticide Cattle Ear Tag, dated May 28, 2008, which has been modified only to change those items (see highlighted copy) that fall under the scope of Pesticide Registration Notice (PRN) 98-10, PRN 97-5 or may be accomplished as Non-notifications, and include:

- 1. Due to a change in the manufacturer's tradename of the applicator device for the ear tag, the applicator name for the ear tags has been changed in two places (pages 2 and 4) on the draft label -

from: "For use with Allflex® Global Applicator with red pin and white clip"
to: "For use with Allflex® Universal Total Tagger with red pin and black clip."

- 2. Delete the long chemical names in the ingredient statement in two places (pages 1 and 2) to only list common chemical name (Beta-cyfluthrin). This is allowed pursuant to PRN 97-5, and described in the Label Review Manual (Page 5-3).
- 3. Change of address to add more specific address (add P.O. Box number) in two places on the draft label (pages 1 and 2).
- 4. Change emergency telephone numbers; we are transitioning to another medical service, but the previous telephone numbers will remain in effect for some time.
- 5. Change the Warranty Statement as directed by the Agency to include the phrase "To the extent consistent with applicable law....."
- 6. Change establishment number (to another approved site) in two places on the draft label (pages 1 and 5).

Reason to Issue: Minor Label Modifications [Notification]

Date: 05/28/2008

Supersedes: 08/07/2007

Page 1 of 6

Pouch

**CYLENCE® ULTRA
INSECTICIDE CATTLE EAR TAG**

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks for Up to Five Months.

		Percent By Weight
Active Ingredients	Beta-cyfluthrin.	8%
	Piperonyl butoxide	20%
Other Ingredients	72%
Total	100%

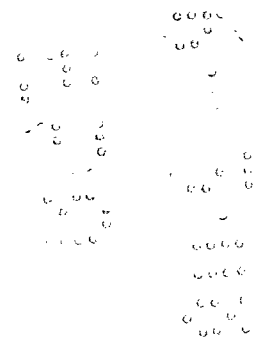
Keep Out of Reach of Children

CAUTION

See Box For Precautionary Statements

Net Contents: 10 Tags - 0.5 oz per tag

Manufactured for
Bayer HealthCare, Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201 U.S.A.



EPA Est. No. 67517-MO-1
EPA Reg. No. 11556-131

NOTIFICATION

JUL 16 2008

7/11

Reason to Issue: Minor Label Modifications [Notification]

Date: 05/28/2008

Supersedes: 08/07/2007

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Box (Front)

CYLENCE® ULTRA

INSECTICIDE CATTLE EAR TAG

For Use with Allflex Universal Total Tagger with red pin and black clip.

For use on Beef and Dairy Cattle (Including Lactating) to Control Face Flies, Horn Flies, Gulf Coast Ticks and Spinose Ear Ticks

- Effective Against Face Flies and Pyrethroid Susceptible Horn Flies for up to 5 months.
- Kills and Repels Face Flies – mechanical vector of *Moraxella bovis* bacteria causing “pink eye” of cattle
- Synergized for extra performance

		Percent By Weight
Active Ingredients	Beta-cyfluthrin.	8%
	Piperonyl Butoxide Technical	20%
Other Ingredients	72%
Total	100%

Keep Out of Reach of Children

CAUTION

See Side Panel for Additional Precautionary Statements

Net Contents: 2 pouches of 10 tags each – 0.5 oz per tag

Bayer HealthCare, Animal Health Division

P.O. Box 390

Shawnee Mission, KS 66201 U.S.A.

Reason to Issue: Minor Label Modifications.[Notification]

Date: 05/28/2008

Supersedes: 08/07/2007

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Box (Side Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

May cause eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wear nonpermeable protective gloves when applying or removing tags. Wash thoroughly with soap and water after use and before eating, drinking or using tobacco.

FIRST AID

- If in Eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.
 - Call a poison control center or doctor for treatment advice.
- If Swallowed:
- Call a poison control center or doctor immediately for treatment advice.
 - Have a person sip a glass of water if able to swallow.
 - Do not induce vomiting unless told to do so by a poison control center or doctor.
 - Do not give anything to an unconscious person.
- If on skin or clothing:
- Take off contaminated clothing.
 - Rinse skin immediately with plenty of water for 15-20 minutes.
 - Call a poison control center or doctor for treatment advice.
- If Inhaled:
- Move person to fresh air.
 - If person is not breathing call 911 or an ambulance then give artificial respiration, preferably mouth-to-mouth if possible.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment, call 1-800-422-9874. For customer service or to obtain product information, including MSDS, call 1-800-633-3796.

Environmental Hazards: This pesticide is toxic to fish. Do not contaminate water when disposing of used tags. Apply this product only as specified on the label.

Reason to Issue: Minor Label Modifications [Notification]

Date: 05/28/2008

Supersedes: 08/07/2007

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Box (Back)

Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application.

For the control of horn flies, face flies, gulf coast ticks, and spinose ear ticks on beef and dairy cattle (including lactating).

All mature animals in the herd should be tagged. For adequate control of horn flies attach one tag per animal. For optimum control of face flies, horn flies, gulf coast ticks, and spinose ear ticks, attach one tag to each ear (two per animal). Replace as necessary. CyLence® Ultra Insecticide Ear Tags have been proven to be effective against face and horn flies for up to five months.

Use the Allflex Universal Total Tagger with the red pin and black clip to apply tags to cattle.

Apply as indicated (Figures 1-4). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tags at end of fly season or prior to slaughter.

(Illustration)

(Illustration)

(Illustration)

(Illustration)

Figure 1

Disinfect pliers prior to use. Place male button onto pin until it projects through the tip.

Figure 2

Slide tag under the clip of the pliers by depressing the lever.

Figure 3

Position tag in the center portion of the front side of the ear.

Figure 4

Apply the tag between the second and third rib cartilage.

Continual exposure of horn flies to a single class of insecticide (e.g. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis.

CyLence® Ultra Cattle Ear Tag contains the pyrethroid insecticide beta-cyfluthrin plus piperonyl butoxide, which is an insecticide synergist.

Reason to Issue: Minor Label Modifications [Notification]

Date: 05/28/2008

Supersedes: 08/07/2007

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Box (Back)

Storage and Disposal:

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool place in original container. Opened pouches containing ear tags should be resealed for storage.

Pesticide Disposal: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty pouch in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned stay out of smoke.

EPA Est. No. 67517-MO-1

EPA Reg. No. 11556-131

Reason to Issue: Minor Label Modifications [Notification]

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Box (Side Panel)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.